IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	:	**James Adkins Froman et al.**
Application No.	:	**10/597,706**
Filed	:	**August 4, 2006**
For	:	**EXTERNAL DEFIBRILLATOR WITH TRAINING MODE AND METHOD OF USE**

APPEAL BRIEF

On Appeal from Group Art Unit 3766

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded August 4, 2006 at reel 018053, frame 0870.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-18. Claims 1-18 are pending in the application and stand finally rejected by the Examiner in the Office action mailed July 14, 2009. The claims being appealed are Claims 1-15.

IV. STATUS OF AMENDMENTS

No amendments were filed in response to the final rejection mailed July 14, 2009. A Notice of Appeal with the requisite fee was filed September 14, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per independent Claims 1 and 15 is an external defibrillator which is selectably usable in a therapy mode for resuscitating a victim of cardiac arrest, or in a training mode for training potential rescuers in the use of the defibrillator during a rescue. Numerous techniques have been developed for training potential rescuers in the use of a defibrillator such as training videos and training systems, but experience has shown that training is most effective when done with the actual defibrillator that is to be used in a rescue. The present invention is directed to such a defibrillator which has a therapy mode for an actual rescue but also has a mode of operation in which a rescue is simulated to train rescuers in the intended use of the defibrillator for resuscitation.

One of the most critical steps performed by the rescuer during use of a defibrillator is correctly applying the electrode pads to the chest of the victim. The electrodes stick to the skin of the victim with a conductive adhesive gel, which is covered by a release liner to protect the gel prior to use. Inexperienced rescuers are often unaware of the release liner and may try to apply the electrodes to the victim without removing the release liners. Training of electrode placement usually starts with a voice prompt which instructs the potential rescuer to remove the

electrodes from their packaging and remove the release liners. A defibrillator of the present invention detects electrode handling prior to placement of the electrodes on the training subject and can identify when the release liner is removed by a state identifier which identifies the degree of electrical conductivity of the electrical path of the electrodes. When a predetermined electrical conductivity is identified during handling of the electrodes, such as a change from a low impedance to a high impedance, the defibrillator recognizes that the release liners have been removed and progresses to the next training state, such as a prompt to apply the electrodes to the patient as shown by the diagram on the electrodes. The potential rescuer is thus fully trained in proper use of the electrodes during the training session, including the critical step of removal of the electrode release liners.

Comparing independent Claims 1 and 15 to the drawings and specification, it is seen that these claims are supported by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

1. An external defibrillator (#10; pg. 5, ln 7-8) selectably usable in one of a therapy mode and a training mode (pg. 6, ln 18-19), when in the training mode, having a plurality of training state notifications (pg. 10, ln 7-12), and adapted for electrical coupling with an electrode (#200; pg. 7, ln 23-26) arrangeable on a release liner (#304; pg. 8, ln 29-32), the electrode electrically conductive and configured for placement on a subject (pg. 7, ln 30 to pg. 8, ln 10), comprising:

an energy source (#22; pg. 5, ln 17-21);

an electrode interface (#17; pg. 5, ln 11-13) responsive to the electrode;

an energy delivery system (#12; pg. 5, ln 8-11) operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface;

a state identifier (#34; pg. 6, ln 7-17), identifying, when the electrode is electrically coupled to the electrode interface, a degree of electrical connectivity along an electrical path including the electrode (#406; pg. 11, ln 10-13);

a controller (#18; pg. 5, ln 22-25), operative in the training mode, prior to placement of the electrode on the subject, to advance the external defibrillator from a first training state to a second training state when the state identifier identifies a predetermined degree of electrical conductivity along the electrical path (pg. 9, ln 30 to pg. 10, ln 7); and

a user interface (#19; pg. 5, ln 26-31), operative in the training mode to issue a training state notification indicating that the external defibrillator has advanced from the first training state to the second training state (pg. 10, ln 7-11; #410; pg. 11, ln 17-19).

15. A method for training a user to operate an external defibrillator, comprising:

providing an external defibrillator selectably usable in one of a therapy mode and a training mode (#400; pg. 11, ln 5-7), the external defibrillator comprising:

an energy source (#22; pg. 5, ln 17-21);

an electrode interface (#17) responsive to an electrode (#200), the electrode arrangeable on a release liner (#304) and configured for placement on a subject (#404; pg. 11, ln 7-10); and

an energy delivery system (#12; pg. 5, ln 8-11) operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface;

when the electrode is coupled to the electrode interface, receiving an input signal from the electrode, prior to placement of the electrode on the subject (#404; pg. 11, ln 8-10);

based on the input signal, identifying a degree of electrical connectivity along an electrical path including the electrode (#406; pg. 11, ln 10-13);

based on the determined degree of electrical conductivity, advancing the external defibrillator from a first training state to a second training state (#408; pg. 11, ln 13-17) and

issuing a training state notification indicating advancement from the first training state to the second training state (#410; pg. 11, ln 17-19).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-6 and 15 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. appl. pub. US 2003/0233129 (Matos) in view of US patent pub. 2003/0199929 (Snyder et al.); and

B. Whether Claims 7-14 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Matos in view of Snyder et al. and further in view of US Pat. 5,275,572 (Ungs et al.).

VII. ARGUMENT

A. Rejection of Claims 1-6 and 15 under 35 U.S.C. §103(a) as being unpatentable over Matos in view of Snyder et al.

Matos describes a system by which a layperson with no medical knowledge or training, a so-called "untrained enabler," is directed to

resuscitate a cardiac arrest victim by a medical professional over a two-way video, voice, and data link. The enabler thus needs to know or understand nothing about the procedure or equipment, as the enabler is acting as no more than "a pair of hands" at the rescue scene which are being completely directed by the remote medical professional. The Matos system has no training mode of operation. The paragraphs of Matos cited by the Examiner for the training mode, [0073]-[0074], [0090] and [0096]-[0099], are silent on this point. Likewise, Snyder et al., which was cited for its showing of an electrode with a release liner, does not show or suggest a defibrillator with a training mode.

As the final rejection shows, the Examiner attempts to overcome this deficiency of the references by rationalizing that the enabler in Matos "is being trained in real-time on how to administer therapy." It is respectfully submitted that this rationalization does not convert the therapeutic operation of the Matos system into a system training mode. The training mode of a medical device, including a defibrillator, is well known to those skilled in the art. See for example US Pat. 5,611,815 (Cole et al.) at col. 3, lines 17-24; US Pat. 6,381,492 (Rockwell et al.) in the abstract; and US Pat. 6,899,103 (Hood et al.) at col. 27, lines 17-21. As well defined by the passage in Hood et al., "a training mode is available which allows a user to simulate various different types of

trauma casualties, and thus allows care givers to attain proficiency in the proper use of the transportable life support system of the present invention." Since the purpose of the training mode is to instruct an operator by means of the simulation of an actual operating situation, it stands to reason that a well-conceived training mode will closely parallel conditions of an actual event, as that is what it is trying to simulate. That does not change the use of a device in an actual event into a training mode of the device. In Matos, no training simulation is shown or suggested, only actual use during a medical emergency. It is therefore respectfully submitted that the Matos and Snyder et al. references, lacking any suggestion of a training mode, are inapplicable to the training mode of the defibrillator of Claim 1.

It is further respectfully submitted that, even if the therapeutic operation of Matos were considered to be a training mode, both references would still fail to render the invention of Claim 1 unpatentable. Claim 1 recites the use of "a controller, operative in the training mode, prior to placement of the electrode on the subject...when the state identifier identifies a predetermined degree of electrical conductivity along the electrical path." In step 880 of FIG. 18E of Matos the medical professional tells the enabler to apply the electrode pad on the patient, including the removal of the release liner ("peel the plastic off the back of

the pad"). The only check or monitoring of this action is a visual one (steps 886 and 887) and a query of the enabler as to whether the electrode pad is properly applied (step 884). No electrical interaction with the electrode is done until step 890, after the electrode is applied. See paragraphs [1517] to [1519] of Matos. At this point a poor electrical signal can be caused by a number of conditions such as excessive chest hair, failure to press the electrode firmly against the skin, dry electrode gel, or failure to remove a release liner, among others. Thus, Matos' medical professional does not make his electrical checks until the cause of a problem has become ambiguous after the electrode is placed on the patient. For this further reason it is respectfully submitted that Matos and Snyder et al. cannot render Claim 1 unpatentable. Claims 2-14, which depend from Claim 1, are patentable by virtue of their dependency.

Claim 15 describes a method for training a user to operate an external defibrillator which is selectably usable in one of a therapy mode and a training mode. Since neither Matos nor Snyder et al. show or suggest a training mode for their systems, it is respectfully submitted that Claim 15 is patentable over these two references. Furthermore, Claim 15 recites that, when an electrode is coupled to the electrode interface of a defibrillator, an input signal is received from the electrode prior to placement of the electrode on a subject. In Matos an enabler at the scene

of a cardiac victim is told to place electrodes on the victim in step 880, which is visually checked by a medical professional over a video link in steps 886 and 887. The medical professional also asks the enabler at the scene whether the electrodes are properly applied in step 884. Input signals are then received from the electrodes after they are applied to the victim, starting with impedance measurements in step 890. No signals are received from an electrode prior to its placement on a subject. For this further reason it is respectfully submitted that Claim 15 is patentable over Matos and Snyder et al.

B. Rejection of Claims 7-14 under 35 U.S.C. §103(a) as being unpatentable over Matos in view of Snyder et al. and further in view of Ungs et al.

Claims 7-14 all depend from Claim 1. Ungs et al. describe a pair of training electrode which can be placed on a CPR mannequin during training. An EKG simulator is connected to the training electrodes so that a defibrillator connected to the electrodes will see an EKG signal produced by the simulator. The defibrillator delivers a shock which is dissipated by the EKG simulator. Use of the training electrodes is described in column 4, lines 59-67 of Ungs et al. It is seen that the EKG signals are not monitored in this passage until after the electrodes are

attached to the CPR mannequin. (It appears that EKG signals are continuously transmitted to the defibrillator as of the time the cable leads 33 are connected to the posts 21 on the pads 13, but they are not to be monitored by the trainee until the pads are placed on the mannequin. See col. 4, lines 22-35. The EKG signals, in any event, tell nothing about the quality of electrode placement, as the signals are the same whether the pads are attached to the mannequin or not.) There is no monitoring or detection of any training state change by the defibrillator prior to placement of the electrodes on a subject as called for by Claim 1. Furthermore, the defibrillator in Ungs et al. appears to have no training mode. The defibrillator in Ungs et al. is operated during training on the CPR mannequin exactly as it operates during an actual rescue of a victim, including delivery of a high voltage shock. It also does not appear to deliver any training state notifications indicating advancement of training states. It is respectfully submitted that for all of these reasons the combination of Matos, Snyder et al., and Ungs et al. do not render Claim 1 or its dependent Claims 7-14 unpatentable.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-6 and 15 are patentable over Matos and Snyder et al. and that Claims 7-14 are patentable over Matos and Snyder et al. in view of Ungs et al. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the July 24, 2009 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 1-15 are the claims involved in the appeal.

1. (original) An external defibrillator selectably usable in one of a therapy mode and a training mode, when in the training mode, having a plurality of training state notifications, and adapted for electrical coupling with an electrode arrangeable on a release liner, the electrode electrically conductive and configured for placement on a subject, comprising:

an energy source;

an electrode interface responsive to the electrode;

an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface;

a state identifier, identifying, when the electrode is electrically coupled to the electrode interface, a degree of electrical connectivity along an electrical path including the electrode;

a controller, operative in the training mode, prior to placement of the electrode on the subject, to advance the external defibrillator from a first training state to a second training state when the state identifier identifies a predetermined degree of electrical conductivity along the electrical path; and

a user interface, operative in the training mode to issue a training state notification indicating that the external defibrillator has advanced from the first training state to the second training state.

2. (original) The external defibrillator according to claim 1, wherein the predetermined degree of electrical conductivity comprises an impedance level.

3. (original) The external defibrillator according to claim 2, wherein the impedance level indicates that the electrode was removed from the release liner.

4. (previously presented) The external defibrillator according to claim 2, wherein the predetermined degree of electrical conductivity indicates that the electrode was removed from a package containing the electrode attached to the release liner.

5. (original) The external defibrillator according to claim 1, wherein the training state notification comprises one of a voice message and a visual prompt.

6. (original) The external defibrillator according to claim 5, wherein the voice message comprises one of a message instructing a user to remove the electrode from the release liner and a message instructing a user to place the electrode on a training apparatus.

7. (previously presented) The external defibrillator according to claim 1, wherein the training mode is selected based on identification of the electrical coupling of the external defibrillator with a training electrode.

8. (original) The external defibrillator according to claim 7, wherein the training electrode comprises:

a conductive attachment layer; and

a conductive metal layer in communication with the conductive attachment layer, the conductive metal layer having a void therein that provides a nonconductive region within the conductive metal layer.

9. (original) The external defibrillator according to claim 8, wherein the electrical path comprises a path through the conductive attachment layer and the release liner.

10. (original) The external defibrillator according to claim 7, wherein the identification of the training electrode is based on an impedance associated with the training electrode.

11. (original) The external defibrillator according to claim 10, wherein the impedance level of the training electrode is based on a resistance value of a resistor coupled in series with the training electrode.

12. (original) The external defibrillator according to claim 7, wherein when the training electrode is attached, the external defibrillator is not operable in the therapy mode.

13. (previously presented) The external defibrillator according to claim 1, wherein, when the defibrillator is in the therapy mode, the subject comprises a human being, and, when the defibrillator is in the training mode, the subject comprises a training apparatus.

14. (original) The external defibrillator according to claim 13, wherein the training apparatus comprises:

a layer having an electrode attachment region defining an area sized to receive the electrode;

a signal conductor disposed proximate the electrode attachment region, the signal conductor operable to provide communication between the electrode and the external defibrillator when the electrode is disposed on the electrode attachment region; and

a two-dimensional representation of a subject having the electrode attachment region arranged thereon in a manner that defines a preferred placement area of the electrode on the subject.

15. (original) A method for training a user to operate an external defibrillator, comprising:

providing an external defibrillator selectably usable in one of a therapy mode and a training mode, the external defibrillator comprising:

an energy source;

an electrode interface responsive to an electrode, the electrode arrangeable on a release liner and configured for placement on a subject; and

an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface;

when the electrode is coupled to the electrode interface, receiving an input signal from the electrode, prior to placement of the electrode on the subject;

based on the input signal, identifying a degree of electrical connectivity along an electrical path including the electrode;

based on the determined degree of electrical conductivity, advancing the external defibrillator from a first training state to a second training state and

issuing a training state notification indicating advancement from the first training state to the second training state.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.